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Dated: 8-26-05 Signature: Mary Murphy  
(Mary Murphy)

Docket No.: CWRU-P01-044  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Sanford D. Markowitz

Application No.: 10/650,112

Confirmation No.: 5888

Filed: August 26, 2003

Art Unit: 1642

For: METHODS FOR TREATING PATIENTS  
AND IDENTIFYING THERAPEUTICS

Examiner: S. L. Rawlings

### INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

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In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

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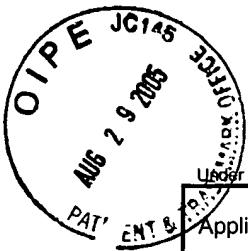
Dated: August 26, 2005

Respectfully submitted,

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PTO/SB/92 (09-04)

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Application No. (if known): 10/650112

Attorney Docket No.: CWRU-P01-044

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	10/650112
				Filing Date	August 26, 2003
				First Named Inventor	Sanford D. Markowitz
				Art Unit	1642
				Examiner Name	S. L. Rawlings
Sheet	1	of	2	Attorney Docket Number	CWRU-P01-044

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA*	US-2004/0005563-A1	01-08-2004	Mack, et al.		
AB*	US-2003/0232350-A1	12-18-2003	Afar, et al.		

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
BA	-WO 99/38881		08-05-1999	Human Genome Sciences Inc.		
BB	-WO 01/75067		10-11-2001	Hyseq, Inc.		
BC	-WO 01/90357		11-29-2001	Genesis Res. Dev. Corp.		
BD	-WO 02/21996		03-21-2002	EOS Biotechnology, Inc.		
BE	-WO 02/30268		04-18-2002	EOS Biotechnology, Inc.		
BF	-WO 02/50301		06-27-2002	Gene Logic, Inc. et al.		
BG	-WO 02/068677		09-06-2002	EOS Biotechnology et al.		
BH	-WO 04/018647		03-04-2004	Case Western Reserve Univ.		

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CA		Alon, U. et al. Broad patterns of gene expression revealed by clustering analysis of tumor and normal colon tissues probed by oligonucleotide arrays. PNAS 96, 745-750 (June 1999).	
CB		Bieller, A. et al. Isolation and Characterization of the Human Forkhead Gene FOXQ1. DNA Cell Biol. 20, 555-561 (2001).	
CC		Deng, G. et al. Methylation of CpG in a Small Region of the hMLH1 Promoter Invariably Correlates with the Absence of Gene Expression. Cancer Res. 59, 2029-2033 (1 May 1999).	
CD		Esteller, M. et al. Detection of Aberrant Promoter Hypermethylation of Tumor Suppressor Genes in Serum DNA from Non-Small Cell Lung Cancer Patients. Cancer Res. 59, 67-70 (1 January 1999).	
CE		GenBank Accession No. W07459 (25 April 1996).	
CF		GenBank Accession No. AI357412 (06 Jan. 1999).	
CG		GenBank Accession No. AI590539 (9 April 1999).	
CH		GenBank Accession No. AI870708 (21 July 1999).	
CI		GenBank Accession No. BAA92054 (16 Feb. 2000).	
CJ		GenBank Accession No. AY007815 (29 Aug. 2000).	
CK		GenBank Accession No. AAG41062 (29 Aug. 2000).	
CL		GenBank Accession No. XM_061091 (31 July 2002).	
CM		Hardy, R.G. et al. Aberrant P-cadherin expression is an early event in hyperplastic and dysplastic transformation in the colon. Gut 50, 513-519 (2002).	
Examiner Signature		Date Considered	

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Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/650112
				Filing Date	August 26, 2003
				First Named Inventor	Sanford D. Markowitz
				Art Unit	1642
				Examiner Name	S. L. Rawlings
Sheet	2	of	2	Attorney Docket Number	CWRU-P01-044

	CN	Herman, J.G. et al. Incidence and functional consequences of hMLH1 promoter hypermethylation in colorectal carcinoma. PNAS 95, 6870-6875 (June 1998).	
	CO	Hibi, K. et al. Molecular Detection of Genetic Alterations in the Serum of Colorectal Cancer Patients. Cancer Res. 58, 1405-1407 (1 April 1998).	
	CP	Kane, M.F. et al. Methylation of the hMLH1 Promoter Correlates with Lack of Expression of hMLH1 in Sporadic Colon Tumors and Mismatch Repair-defective Human Tumor Cell Lines. Cancer Res. 57, 808-811 (1 March 1997).	
	CQ	Kobayashi, A. et al. Molecular Cloning and Functional Characterization of a New Cap'n' Collar Family Transcription Factor Nrf3. J. Biol. Chem. 274, 6443-6452 (5 March 1999).	
	CR	Markowitz, S. et al. Inactivation of the Type II TGF-\$\beta\$ Receptor in Colon Cancer Cells with Microsatellite Instability. Science 268, 1336-1338 (1995).	
	CS	Radice, G.L. et al. Precocious Mammary Gland Development in P-Cadherin-deficient Mice. J. Cell Biol. 139, 1025-1032 (17 Nov. 1997).	
	CT	Scott, D.A. et al. Refining the DFNB7-DFNB11 deafness locus using intragenic polymorphisms in a novel gene, TMEM2. Gene 246, 265-274 (2000).	
	CU	Shimoyama, Y. et al. Molecular Cloning of a Human Ca2+-dependent Cell-Cell Adhesion Molecule Homologous to Mouse Placental Cadherin: Its Low Expression in Human Placental Tissues. J. Cell Biol. 109, 1787-1794 (1989).	
	CV	Unigene Hs.157601, Homo sapiens transcribed sequences.	
	CW	Veigl, M.L. et al. Biallelic inactivation of hMLH1 by epigenetic gene silencing, a novel mechanism causing human MSI cancers. PNAS 95, 8698-8702 (July 1998).	
	CX	Weber, G.F. The metastasis gene osteopontin: a candidate target for cancer therapy. Biochim. Biophys. Acta. 1552, 61-85 (2001).	
	CY	Wines, M.E. et al. Identification of Mesoderm Development (mesd) Candidate Genes by Comparative Mapping and Genome Sequence Analysis. Genomics 88-98 (2001).	
	CZ	Wong, I.H.N. et al. Detection of Aberrant p16 Methylation in the Plasma and Serum of Liver Cancer Patients. Cancer Res. 59, 71-73 (1 Jan. 1999).	
	CA1	Zhang, J.-S. et al. Keratin 23 (K23), a Novel Acidic Keratin, Is Highly Induced by Histone Deacetylase Inhibitors During Differentiation of Pancreatic Cancer Cells. Genes Chromosomes Cancer 30, 123-135 (2001).	
	CB1	De Plaen E, et al. Immunogenetics 1994; 40: 360-9, Structure, chromosomal localization, and expression of 12 genes of the MAGE Family	
	CC1	Burgess WH et al. J Cell Biol 1990 Nov; 111 (5Pt 1): 2129-38, Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue	
	CD1	Bowie JU, et al. Science 1990 Mar 16; 247 (4948): 1306-10, Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions	
	CE1	Lazar E, et al. Mol Cell Biol 1988 Mar; 8 (3): 1247-52, Transforming Growth Factor \$\alpha\$: Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities	
	CF1	Skolnick J, et al. Trends Biotechnol 2000 Jan; 18 (1): 34-9, From genes to protein structure and function: novel applications of computational approaches in the genomic era	
	CG1	Takada I, et al. Mol. Endocrinol. 2000; 14 (5): 733-40, Alteration of a Single Amino Acid in Peroxisome Proliferator-Activated Receptor-\$\alpha\$ (PPAR\$\alpha\$) Generates a PPAR\$\delta\$ Phenotype	
	CH1	Guo HH, et al. Proc. Natl. Acad. Sci. USA. 2004 Jun 22; 101 (25): 9205-10, Protein tolerance to random amino acid change	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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